

**R E M A R K S**

Claims 1-10 are pending in the present application. Claims 1, 8 and 10 have been amended. Claims 7 and 11 have been cancelled. No new matter has been entered by way of the above amendments. As such, entry and consideration thereof are respectfully requested.

**Rejections under 35 U.S.C. § 112**

Claim 10 has been rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph for lack of enablement. On page 2 of the Office Action, the Examiner asserts that the invention of claim 10 is only enabled for a method of producing anesthesia and pre-anesthesia muscle relaxation and that the specification does not enable the treatment of any disease, disorder or condition, which is responsive to modulation of the GABA receptor complex. Claim 10 has been amended herein to be drawn to the conditions recited in claim 11, which was not rejected, and which is drawn to the conditions indicated as being enabled. Claim 11 has been concomitantly cancelled. Withdrawal of the rejection is respectfully requested.

Claims 10 and 11 have been further rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for lacking enablement with regard to the prevention of the recited conditions. Claim 10 has been further amended to be drawn to the treatment or alleviation of the recited conditions, with the recitation of “prevention” being deleted. Withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. § 102**

1) Claims 1-7 and 9-11 have been rejected under 35 U.S.C. §102(b) as being anticipated by Teuber '728. The Examiner asserts that Teuber '728 teaches a range of compounds, which fall within the scope of claim 1.

Claim 1 has been amended to define, R' as alkoxyalkyl, alkoxyalkenyl or alkoxyalkynyl. Thus, the compounds of the instant invention differ from the disclosure of Teuber '728 by having a having a “lower” hydroxy group substituted with a hydrocarbon chain. As such, the instant claims are not anticipated by Teuber '728 and withdrawal of the rejection is respectfully requested.

Claims 1, 3, 4, 7 and 9-11 have been rejected under 35 U.S.C. 102(b) as being anticipated by Teuber '98. Applicants traverse this rejection and withdrawal thereof is respectfully requested. The compounds disclosed in the Teuber '98 reference differ from the present invention due to the "Y"-linker between the phenyl group and the N-containing heterocyclic ring, which is present in the compounds of Teuber '98. As such, withdrawal of the rejection is respectfully requested.

#### **Rejections under 35 U.S.C. §103**

Claim 8 has been rejected under 35 U.S.C. §103 as being obvious over Teuber '728. The Examiner asserts that it would have been obvious to produce the specifically recited compounds of claim 8 based on the compounds of Teuber '728 having a similar structure. Applicants traverse this rejection and withdrawal thereof is respectfully requested. Attached hereto as Exhibit I is a comparison of the binding and efficacy of compound **1f** of the invention and compound **1cc** of Teuber '728, i.e. the closest compound of the prior art. The data of Exhibit I demonstrate the unexpected superior binding and efficacy associated with the instant invention compared to the compounds of Teuber '728. As such, the invention of claim 8 is not obvious over the disclosure of Teuber '728 and withdrawal of the rejection is respectfully requested.

#### **Obviousness-type double patenting**

Claims 1-4, 6 and 9-11 have been rejected for non-statutory obviousness-type double patenting as being obvious over claims 1, 7, and 10-12 of USP 6,649,609. Applicants traverse this rejection and withdrawal thereof is respectfully requested. USP 6,649,609 corresponds to Teuber '728. As discussed above, the instant invention possesses unexpected, superior properties compared to the compounds disclosed in Teuber '728/USP '609. As such, the invention of claims 1-4, 6 and 9-11 is not obvious over claims 1, 7 and 10-12 of US '609 and withdrawal of the rejection is respectfully requested.

In view of the above amendments and Remarks, Applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By   
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Attachment: Exhibit 1

**Exhibit I**

**Test results**

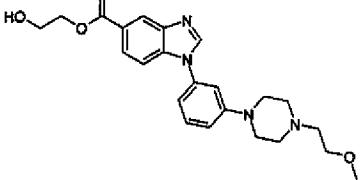
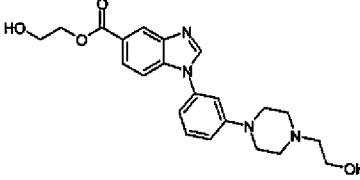
5 In the table below, compound **1f** of the invention (2-hydroxyethyl 1-(3-(4-(methoxyethyl)-1-piperazinyl)-phenyl)-benzimidazole-5-carboxylate) is compared to the closest prior art compound **1cc** of Teuber '00 (2-hydroxyethyl 1-(3-(4-(2-hydroxyethyl)-1-piperazinyl)-phenyl)-benzimidazole-5-carboxylate of WO 00/78728).

10 The compounds are tested with respect to *in vitro* and *in vivo* binding activity (inhibition of  $^3\text{H}$ -flunitrazepam ( $^3\text{H}$ -FNM) binding) and *in vivo* efficacy (PTZ-induced clonic convulsions).

15 The tests are performed as described in the Test Method paragraphs in the specification of the patent application.

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**Table 1**

Compound	<i>In vitro</i> binding $IC_{50}$ ( $\mu\text{M}$ )	<i>In vivo</i> binding $ED_{50}$ (mg/kg)	Effect on PTZ-induced clonic convulsions $ED_{60}$ (mg/kg)
Compound <b>1f</b> of the invention 	0.056	6.5	<1.0
Prior art compound <b>1cc</b> of Teuber '00 	0.028	18	22